MARYLAND Department of Health

Tier 2 and Non-Preferred Antipsychotics For Patients Age 18 Years and Older

The following clinical criteria must be met to obtain prior authorization (PA) for non-preferred and Tier 2 antipsychotics. All other existing policies such as those regarding generic substitution and quantity limit (including dose optimization) continue to apply to these drugs as well.

Note: Patient will be grandfathered, if patient has been on the prescribed drug for greater than 30 days in the previous 120 days excluding any emergency supplies obtained through the Conduent help desk.

Criteria for immediate approval upon review:

- The medication was started on an inpatient unit/other acute care setting and the patient was discharged within the last 60 days; **OR**
- The prescriber furnishes documentation that the patient has experienced adverse effects, allergic reactions, has a contraindication to, or failed to respond to each of the preferred antipsychotic medications.

Other requests will be evaluated based on the following criteria:

- The patient has FDA indicated diagnosis for the requested medication; AND
- The requested medication complies with FDA-labeling FDA –labeling for indication, dosage and administration frequency-
- The patient has had an adequate trial (at least 6 weeks at recommended dose) of at least one preferred antipsychotic drug.

The use of pharmaceutical samples and emergency supplies authorized by Xerox will not be considered when evaluating the patient's medical condition or prior prescription history for drugs that require prior authorization.

All requests are reviewed by a psychiatric clinical pharmacist at the Maryland Medicaid Pharmacy Program or its designee.

Requests for specific drugs/dosage forms:

Alternate dosage form: When a drug is available in an oral tablet or capsule dosage form, all other dosage forms (excluding injectable) will only be approved if the patient has a documented resistance or inability to ingest the oral tablet or capsule.

Once daily dosage form: Medications available in an extended duration dosage form or with extended half lives will only be approved for once daily administration as per FDA labeling.

Invega® oral tablet: Authorization will only be approved if the patient has hepatic dysfunction that prevents risperidone metabolism to the active metabolite or a genetic polymorphism for CYP2D6 that classifies the patient as a "slow metabolizer" of risperidone.[1]

Multiple antipsychotics: If a patient has an existing authorization for a non-preferred or tier 2 antipsychotic at the time authorization is sought for a second tier 2 or non-preferred antipsychotic, the authorization for the initially approved antipsychotic will be adjusted to expire 90 days after the approval of the second agent in order to allow an adequate titration period between medications. Two or more tier 2 or non-preferred antipsychotics will not be authorized for extended time.

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[1]Per Package insert for Invega Sustenna® "For patients who have never taken oral paliperidone or oral or injectable risperidone, tolerability should be established with oral paliperidone or oral risperidone prior to initiating treatment with INVEGA® SUSTENNA®."

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Additional monitoring recommendations:

Note: Due to certain risk factors with these agents, the following monitoring parameters are indicated: BMI, BP, Fasting Glucose, Fasting Lipid Profile, EKG (when indicated), and an assessment of abnormal involuntary movements (ex. AIMS or DISCUS) and an assessment of family and personal history for cardiac risk factors.

Recommended Monitoring by the American Diabetes Association and American Psychiatric Association:

Parameter/Frequency	Baseline	4 weeks	8 weeks	12 weeks	Every 3 months	Yearly
BMI	x	x	x	x	x	x
Waist Circumference	x					x
BP	x			x		x
FBG/HbA1c	x			x		x
Fasting Lipids	x			x		x

BMI – Body Mass Index = 703 x wt (pounds)/height^2 (inches) BP – Blood Pressure FBG – Fasting Blood Glucose

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